

### **REMARKS**

Claims 1-10 are the pending claims in the present application. Applicants cancel, without prejudice, claims 5, 6, and 10. Applicants add new claims 11-15. Support for the subject matter of these claims is found throughout the specification. Specifically, support can be found on page 9, lines 9-21.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

1. Applicants note that the previously filed amendments have been entered in full.
2. Claims 1-8 and 10 are currently under examination.
3. Applicants note with appreciation that any rejection of record that was not expressly repeated in this action has been overcome and withdrawn.
4. Claims 1-8 and 10 are rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-19 of US Patent No. 6,207,718. Furthermore, claims 1-8 and 10 are rejected under 35 U.S.C. 103(a) as allegedly being obvious over US Patent No. 6,207,718. Applicants traverse this rejection.

Applicants previously indicated their willingness to submit a terminal disclaimer, if necessary, upon indication of allowable subject matter. However, in response to this and other grounds of rejection, Applicants have amended the claims to more particularly point out certain embodiments of the invention. Applicants' amendments are not in acquiescence to the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. Applicants' amendments are believed to obviate the need for a terminal disclaimer, and reconsideration and withdrawal of this rejection are requested.

5. Claims 1-8 and 10 are rejected under 35 U.S.C. 103(a) as allegedly being obvious over Pepinsky et al. in view of Easton et al., and further in view of Usala et al. Applicants traverse this rejection, and furthermore Applicants contend that the rejection is moot in light of the amended claims.

Applicants maintain that the combination of references cited by the Examiner fail to render the claimed invention obvious. Although broadly enabling, the teachings of Pepinsky et al. fail to disclose the particular combinations of elements that characterize the claimed invention. These deficiencies are not overcome by Easton et al. or Usala et al. which provide nothing more than an invitation to one of skill in the art to attempt to arrive at Applicants' invention. Accordingly, these combinations of references are insufficient to undermine the patentability of Applicants' invention.

Applicants contend that a valid patent may issue for a nonobvious species related to a prior patented invention, even though the improvement falls within the claims of that prior patent. A prior genus which does not explicitly disclose a species does not anticipate a later claim to that species. This position is well supported by the holdings of the Federal Circuit. See, for example, *Corning Glass Works v. Sumitomo Electric U.S.A.*, 868 F.2d 1251, 1262, 9 USPQ2d 1962, 1970 (Fed. Cir. 1989).

Applicants contend that the relationship between the pending claims and the cited art is largely analogous to the factual situation in the above example. Applicants assert that the presently claimed invention is a species which is unobvious and patentable over the generic teachings of Pepinsky et al.

Although Pepinsky et al. is broadly enabling, Pepinsky et al. fail to teach the benefits of the particular combinations of elements set forth in the pending claims. That is, although Pepinsky et al. broadly teaches various compositions comprising lipophilic hedgehog polypeptides, Pepinsky et al. provide no motivation to specifically select the particular concentrations of hedgehog polypeptide, the particular buffers, the particular pH range, or the particular delayed release characteristics presently claimed. MPEP 2144.08 outlines the guidelines for determining that a reference renders an invention obvious and directs the Examiner to "determine whether one of ordinary skill in the relevant art would have been motivated to make the claimed invention as a whole, i.e., to select the claimed species or subgenus from the disclosed prior art genus." Applicants contend that Pepinsky et al. fail to provide motivation to select the specific combination of elements presently claimed.

The Examiner has provided additional references to allegedly support this rejection. However, the additional references cited by the Examiner do not overcome the deficiencies of Pepinsky et al. These additional references provide only general guidance and provide no motivation to select from amongst the teachings of Pepinsky et al. to arrive at the presently claimed invention. Accordingly, neither Pepinsky et al. nor Pepinsky et al. in combination with Easton et al. and Usala et al. render the presently claimed invention obvious.

Applicants maintain that Pepinsky et al. fail to satisfy the criteria necessary for rendering obvious Applicants' invention. Nevertheless, to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended the claims to more particularly point out certain embodiments of the invention. Applicants' amendments are not in acquiescence to the rejection, and Applicants reserve the right to prosecute claims of similar or differing scope. The amended claims are directed to particular delayed release compositions of modified hedgehog proteins. Applicants maintain that, prior to the present application, the cited references provided no motivation to guide one of skill in the art in selecting the particular combination of elements presently claimed. Reconsideration and withdrawal of this rejection are respectfully requested.

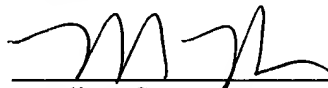
### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants submit that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

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Respectfully Submitted,



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